



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0078]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal

Drug User Fee Act Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the paperwork burden of animal drug sponsors to fill out the Animal Drug User Fee Act (ADUFA) cover sheet.

DATES: Submit either electronic or written comments on the collection of information by

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to

<http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850,

[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

# Animal Drug User Fee Cover Sheet--(OMB Control Number 0910-0539)--Extension

Under section 740 of the FD&C Act (21 U.S.C. 379j-12), as amended by ADUFA (Pub. L. 108-130), FDA has the authority to assess and collect for certain animal drug user fees. Because the submission of user fees concurrently with applications and supplements is required, review of an application cannot begin until the fee is submitted. The types of fees that require a cover sheet are certain animal drug application fees and certain supplemental animal drug application fees. The ADUFA cover sheet (Form FDA 3546) is designed to provide the minimum necessary information to determine whether a fee is required for the review of an application or supplement, to determine the amount of the fee required, and to assure that each animal drug user fee payment and each animal drug application for which payment is made is appropriately linked to the payment that is made. The form, when completed electronically, will result in the generation of a unique payment identification number used in tracking the payment. FDA will use the information collected to initiate administrative screening of new animal drug applications and supplements to determine if payment has been received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

FD&C Act Section amended by ADUFA	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
740(a)(1)	3546 (Cover Sheet)	17	1 time for each application	17	1	17

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are new animal drug applicants or manufacturers. Based on FDA's database system, there are an estimated 173 manufacturers of products or sponsors of new animal drugs potentially subject to ADUFA. However, not all manufacturers or sponsors will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the average number of

submissions received by FDA in fiscal years 2011-13. The estimated hours per response are based on past FDA experience with the various submissions. The hours per response are based on the average of these estimates.

Dated: January 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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